



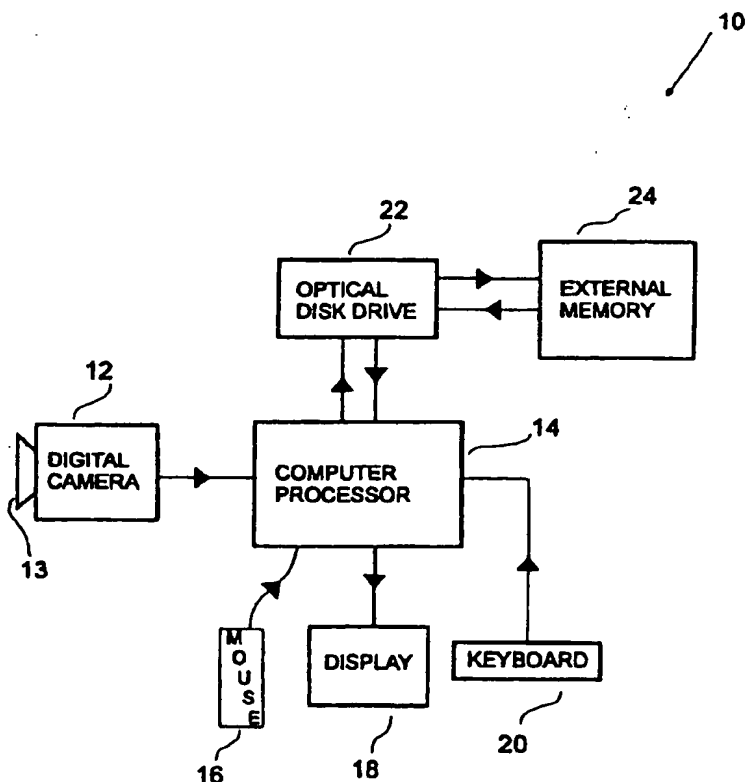
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 5/00	A1	(11) International Publication Number: WO 97/47235 (43) International Publication Date: 18 December 1997 (18.12.97)
(21) International Application Number: PCT/IL97/00187 (22) International Filing Date: 10 June 1997 (10.06.97) (30) Priority Data: 118634 11 June 1996 (11.06.96) IL (71) Applicant (for all designated States except US): J.M.I. LTD. [IL/IL]; Brachyahu Street 10, 96225 Jerusalem (IL). (72) Inventors; and (75) Inventors/Applicants (for US only): SMITH, Yoav [IL/IL]; Hadishon Street 4, 96956 Jerusalem (IL). LEVI, Noam [IL/IL]; Haran Street 3, 92466 Jerusalem (IL). (74) Agent: FRIEDMAN, Mark, M.; Samueloff Building, Hao- manim Street 7, 67897 Tel Aviv (IL).	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report.	

(54) Title: DERMAL DIAGNOSTIC ANALYSIS SYSTEM AND METHOD

(57) Abstract

Dermal diagnostic analysis system and method are provided which may be used for quantifying the visual appearance of skin disorders such as melanoma. The system comprises an imaging element (12) for capturing an image of a skin region; a processing element (14) for converting the captured image to digital image information for analysis, display and storage; and a display element (18) for displaying the digital image information, wherein the digital image information is provided on the display element as border outline of a dark area within the skin region in accordance with a predefined set of parameters; and the digital image information including aspects of the displayed border outline such as its contour, and skin color variations of the area along a pre-selected section line segment, wherein the skin color variations are normalized with respect to a reference portion of the captured skin region image.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

DERMAL DIAGNOSTIC ANALYSIS SYSTEM AND METHOD

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to medical diagnostic equipment and methods, and more particularly, to a dermal diagnostic analysis system and
5 method employing digital analysis of skin photographs of patients to detect changes in lesions, moles, etc., per a pre-defined set of useful analysis parameters.

The prior art includes examples of image analysis of human skin images, and several applications exist, such as for medical diagnostic
10 purposes and identification of individuals.

For example, US Patent 4,699,149 to Rice disclose apparatus for the identification of individuals by scanning a region of the skin to detect the position of subcutaneous blood vessels by measurement of a parameter such as the reflection of incident radiation.

15 In US Patent 5,241,468 to Kenet, there is disclosed an apparatus for spectrally enhancing the image of the skin, to detect melanoma or other conditions creating a dermal pigment. The apparatus includes means for increasing the color saturation.

In US Patent 5,230,025 to Fishbine et al, there is disclosed an
20 identification image recording apparatus for generating data characteristics of fingerprints and recording them.

US Patent 5,195,145 to Backus et al discloses apparatus and methods to scan and record the skin surface topography, and can be used to scan fingerprints for identification purposes.

25 US Patent 5,130,935 to Takiguchi discloses color image processing apparatus for correcting the color image in a region on a representative value and measured quantity.

US Patent 4,947,443 to Costello discloses a method of fingerprint scanning to verify a person's identity relative to topographically-related
30 physical skin surface characteristics.

US Patent 4,805,233 to Denyer discloses a skin-pattern recognition method and device for authenticating a person by comparing information taken from current and previous skin images.

US Patents 3,668,633 and 3,614,737 to Sadowsky disclose an apparatus for identifying an individual by a linear light scanner producing a shadow effect unique to the individual. A designated skin area is positively oriented to improve accuracy.

Melanoma, one of the less common forms of skin cancer, also claims the highest rate of fatalities. In the US alone, about 600,000 white males contract skin cancer every year, and about 1% die of the disease. Melanoma accounts for 75% of skin cancer related deaths, based on National Cancer Institute data. Melanoma progresses via several stages, beginning with external changes in the shape or color of existing spots or moles, at which stage it is possible to successfully treat 99% of the cases.

At a more developed stage, the cancerous cells penetrate the lymphatic system, eventually entering the blood system and organs. At these later stages, recovery rates are very poor, while at the earlier stages, proper detection leads to high recovery rates. High-risk victims include fair skinned people in warm climates.

Diagnosis and treatment of melanoma are characterized by stages which include identification of the external signs, such as changes in the size or color of an existing spot or mole. After examination by a family doctor, the patient is referred to a dermatologist or plastic surgeon for further examination, where the mole appears suspicious, these specialists will either keep it under observation, or call for biopsy to be performed.

In about 85% of cases of suspicious-looking spots and moles, the doctor is not sure whether to perform a biopsy or not. Because of the many parameters involved in visual observation of the changes in these skin disorders, it would be desirable to provide a tool to assist the doctor in making this determination.

US Patent 5,291,889 to Kenet discloses an apparatus for positioning a live body surface image in relation to a stored image to allow for observation over time for diagnostic purposes. A comparison of the images over time is critical for proper diagnosis of the patient, and the
5 Kenet patent allows for an operator to perform alignment of a real and stored image. However, this alignment procedure is performed manually, and is complicated by the need to superimpose, intermingle or juxtapose the images. Therefore, the procedure is time-consuming and costly.

Thus, it would be desirable to provide a simple, comprehensive and
10 cost-effective system for identification and diagnosis of skin disorders, for use by skin specialists.

SUMMARY OF THE INVENTION

Accordingly, it is a principal object of the present invention to overcome the disadvantages associated with the complexity of prior art
15 skin diagnostic systems, and provide a diagnostic analysis tool for quantifying the visual appearance of skin disorders over a range of criteria for analysis purposes.

In accordance with a preferred embodiment of the present invention, there is provided a dermal diagnostic analysis system
20 comprising: an imaging element for capturing an image of a skin region; a processing element for converting the captured image to digital image information for analysis, display and storage; and a display element for displaying the digital image information, wherein the digital image information is provided on the display element as border outline of a dark
25 area within the skin region in accordance with a pre-defined set of parameters, the digital image information including aspects of the displayed border outline such as its contour, and skin color variations of the area along a pre-selected section line segment, wherein the skin color

variations are normalized with respect to a reference portion of the captured skin region image.

In a preferred embodiment, the dermal diagnostic analysis system is provided as a combination of a high resolution digital camera, computer processor and data storage facility, and color screen display. The camera is focused on a region of interest on the skin of a patient, such as a spot, mole or lesion, and the computer processor receives the captures image. In the same skin region, there is placed a fixed size label having a reference color, which forms part of the captured image and is processed together with the skin image. The reference color label enables the system to maintain color uniformity and convey the actual dimensions of the displayed skin image, despite differences in lighting conditions and camera angle. Thus, when the health specialist takes several images of the skin over a period of time, respectable skin observation is achieved.

The displayed image comprises digital image information which provides a border outline of a dark area on the skin in accordance with a pre-defined set of parameters. Thus border outline is analyzed for certain aspects of its contour, such as the size and largest distance between two points thereon, and the skin color variation along a pre-selected section line segment.

The digital image information can also be analyzed with respect to the asymmetrical shape of the lesion, and irregularity of its contour. A histogram can be developed for the color components appearing in a chosen skin area.

The invention provides a comprehensive solution to the problems encountered by skin diagnostic specialists, in maintaining a consistent set of visual images for observations over time, so as to properly diagnose visual changes in the skin. The system provides acquisition and storage of patient images, using the digital camera to provide direct conversion of patient images, without intermediary scanning. Color constancy is

maintained despite varying lighting conditions via normalization of the color components of the image with respect to the reference color label, having a fixed size. A full-featured image database management facility is integral to the system. Thus the inventive system is an advanced tool
5 which provides a comprehensive diagnostic picture, including contour analysis, color component analysis, and a rate of change analysis.

Using the system, patient image data can be tracked over time and successive images of the same lesion can be examined side-by-side, or by overlay techniques, with zoom close-up views. The diagnostic analysis can
10 be performed by quantifying the visual appearance of the lesion over a range of criteria. These measurements can be analyzed for diagnostic significance using graphic displays. A list of relevant diagnostic and treatment options can be displayed, specific to the configuration observed. The analysis can be customized to reflect recent research methods, or
15 previous experience in clinical treatments.

Other features and advantages of the invention will become apparent from the following drawings and description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with
20 reference to the accompanying drawings, wherein:

FIG. 1 is a schematic block diagram of a dermal diagnostic analysis system constructed and operated in accordance with the principles of the present invention;

FIG. 2 is an illustration of the physical layout of the Fig.1 system,
25 showing a specialist taking a patient's skin image;

FIG. 3 illustrates a typical system display screen;

FIG. 4 shows a flowchart for establishing the border outline around the dark area on the skin;

FIG. 5 shows a flowchart for finding the closed list of adjacent border points around the lesion area on the skin;

FIG. 6 shows a flowchart for finding the degree of asymmetry associated with the skin image;

5 FIG. 7 shows a flow chart for finding the degree of irregularity of the skin lesion;

FIGs. 8-9 show, respectively, a typical display screen of a skin image, and a graphical representation of a color distribution analysis performed on the image;

10 FIG. 10 shows a histogram representation of the parameters of interest relating to a skin lesion under study;

FIGs. 11-12 illustrate typical display screens of a skin image, respectively, showing former and more recent versions of the skin area under study;

15 FIG. 13a-b illustrate a combined flowchart for finding the number of lesions on a particular skin region, and their related characteristic parameters;

FIG. 14 illustrates a flowchart for identifying and locating the label which is used to calibrate the image; and

20 FIG. 15 illustrates a flowchart for color correction.

FIG. 16 is a schematic illustration of another embodiment of a dermal diagnostic analysis system according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

25 The present invention relates to dermal diagnostic analysis system and method for quantifying the visual appearance of skin disorders. Although the invention is herein described with reference to melanoma, it may be used for quantifying and monitoring other forms of skin disorders such as psoriasis as well as burns, injuries and the like.

Referring now to Fig. 1, there is shown a schematic block diagram of a dermal diagnostic analysis system 10 constructed and operated in accordance with the principles of the present invention. System 10 preferably comprises a high-resolution digital camera 12, such as kodak
5 DCS 420, the camera having a lens 13, a computer processor 14 such as a personal computer having 32 MB RAM with a 1.3 GB Hard Disc, and high speed processor, such as Intel Pentium. Preferably, standard computer peripherals such as mouse 16, color display screen 18, and keyboard 20 are connected to computer 14. Also connected to computer
10 14 is an optical disc drive 22, having a 230 MB storage capacity. An external system memory 24 is connected to drive 22.

In Fig. 2, there is illustrated a physical layout of the inventive dermal diagnostic analysis system 10. Camera 12 is focused on a region of interest on the skin of a patient 28, such as a spot 28, mole or lesion,
15 and computer processor 14 receives the captured image, by data acquisition of a bitmap file. Preferably, each data point in the bitmap file contains information relating to three color components for representing the skin image. These colors are typically chosen as red, green and blue (RGB).

20 As part of the novel design of dermal diagnostic analysis system 10, there is provided a calibration subsystem for two-dimensional scaling of the skin image, independent of the camera photo angle or patient pose and distance from the camera. The calibration subsystem also provides color correction of the skin image. In order to achieve this, there is placed a
25 label 30 having reference colors on the skin area under study. The label 30 forms part of the captured image and is processed together with the skin image. The reference color label 30 enables system 10 to maintain color uniformity of the displayed skin image, despite differences in lighting conditions. This is especially useful when the health specialist 32

takes several images of the skin over a period of time, for repeatable observation of the skin condition.

The calibration subsystem automatically locates the reference color label 30 within the skin image, by execution of a search algorithm (see 5 flowchart, Fig. 14). The two-dimensional scaling of the image is then performed, and color correction is then performed by execution of the algorithm shown in Fig. 15.

In Fig. 3, there is illustrated a typical display screen of a skin image 35, comprising digital image information which provides a border outline 10 of a dark area on the skin in accordance with a pre-defined set of parameters. The border outline is analyzed for certain aspects of its contour, such as the size and largest distance between two points thereon, and the skin color variations along a preselected section line segment.

As shown at the bottom of Fig. 3, there is a "sliding" segment 37 15 of the display which enables the user to scan all the previously collected photographic images associated with a particular patient, to assist in choosing the image to be studied.

In Fig. 4, there is shown a flowchart representing the computer processor 14 operation in establishing the border outline around the dark 20 area on the skin. In start block 40, the system initializes itself for processing the digital information contained in the bitmap of image points provided with the captured image. In block 44, the color range of interest is defined by selecting points P1, P2 within the image bitmap. In block 46, a line L is defined along which the bitmap is searched to find the border 25 of the image, starting with point P1 to the image edge. In block 48, processor 14 reads the next border point along line L into variable "a". In decision block 50, it is determined whether point "a" is inside the bitmap, and if "NO", no border has been found, since the lesion must be inside the bitmap. If "YES", block 54 operates to find a closed list of adjacent 30 border points including point "a". In decision block 56, it is determined

whether the closed list surrounds points P1, P2. If "NO", the system repeats the search procedure in block 48. If "YES", the list of border points is displayed as the lesion border.

In Fig. 5, there is shown a flowchart representing the computer processor 14 operation in finding the closed list of adjacent border points around the lesion area on the skin. The algorithm finds several closed lists of border points and chooses from them the closed list which surrounds the area of interest. An auxiliary list "options" is used to ignore irrelevant border points which are connected to the list.

10 After start block 60, a list L is defined in block 62 as the list of adjacent border points, and in block 64, the first border outline point "a" is stored in list L. In block 66, point "a" is marked as an occupied point, and in block 68, the group of unoccupied points surrounding "a" are defined as belonging to "A".

15 In decision block 70, a query is made to see if set "A" is empty, and if not, in block 72, a point "c" is chosen from the group "A". In block 74, to an auxiliary list "options" there are added all points in "A" excluding "c". In block 76, point "a" is set to contain "c", and operation returns to block 64, where point "a" is stored in list L, and the operation
20 continues.

In decision block 70, if set "A" is empty, decision block 78 is entered, and if the list L is completed, it is transferred to output in block 80. If not, in block 82, there is inserted into "b" the last point in list "options" which is not "a". The list L is truncated in block 84 by
25 removing all points non-adjacent to "b", and in block 86, all the removed points are marked as unoccupied. In block 88, "a" is set to contain "b", and operation returns to block 64, where point "a" is stored in list L, and then operation continues.

As will be appreciated by those skilled in the art, the skin lesions
30 may be represented by an image in which the borders are unclear, and

thus it will be difficult for the algorithms of Figs. 4-5 to determine the border automatically via the bitmap. For this situation, the dermal diagnostic analysis system 10 is provided with a manual method of drawing the border outline on display screen 18 using the mouse 16 under control of computer 14. Once this is done, the standard image parameters can be analyzed as with the border outline achieved via automatic processing.

In Fig. 6, there is shown a flowchart representing the computer processor 14 operation in finding the degree of asymmetry associated with the skin image. Once the border outline points have been calculated per the flowchart in Figs. 4-5, these are provided in start block 90. In block 92, a search is made in the list of adjacent border points to find two points Po, P1 which are spaced apart a maximum distance. In block 94, the lesion area is computed, and stored in "S". In block 96, a variable S1 is used to hold the value of the lesion area under a section line extending between Po and P1. In block 98, a variable S2 is used to hold the lesion area above the section line extending between Po and P1. In block 100, the asymmetry is computed according to the formula:

$$\frac{|S1-S2| \times 100}{S}$$

This parameter gives an indication of degree of lesion asymmetry.

In Fig. 7, there is shown a flowchart representing the computer processor 14 operation in finding the degree of irregularity of the skin lesion. In block 104, the lesion perimeter P is computed, and in block 106, the lesion diameter D is computed as the distance between points Po and P1, which were previously determined. In block 108, the lesion area is

computed and is stored in "S", and in block 110, the relationship for the measure of irregularity is given by the parameter: $PD/4S$.

In Figs. 8-9, there are illustrated, respectively, a typical display screen of a skin image, and a graphical representation of a color distribution analysis performed on the image. Using the computer 14 and mouse 16, a section line Po-P1 is drawn on the skin image of Fig. 8, and the points along the section line corresponding to the data point in the bitmap file are selected for color distribution analysis. As shown in Fig. 9, The color distribution values are displayed graphically along the section line, and pointer 112 determines the location of point P in Fig. 8. The color information is especially important for diagnostic purposes. For example, if the lesion is analyzed over time, changes in color distribution may be recognized, indicating activity in the skin lesion area, with diagnostic implications.

The dermal diagnostic analysis system 10 of the present invention features a calculation of the average color within the skin lesion (preferably based on the three color components RGB). In addition, the average color in the skin area nearby the lesion is also calculated. The average color value serves as a useful parameter in diagnostic efforts to monitor color changes in the lesion, which are distinguishable from color changes in the surrounding skin area, due to natural color changes, tanning, etc.

In Fig. 10, there is illustrated a histogram representation of the parameters of interest in connection with a skin lesion under study. This display feature enables comparison of these parameters over a period of time, such that during each visit to the dermatologist or other health professional, the parameters of the lesion can be viewed in relation to their time progression. Preferably, the parameters available for display in this fashion are:

1) area

- 2) perimeter
- 3) diameter
- 4) color
- 5) asymmetry
- 5 6) irregularity

Display of the time progression of these parameters is an important aspect in the diagnostic method, since the skin lesion can be displayed over time and compared in relation to quantifiable data with verifiable dates.

Another method for of comparison of skin lesions can be achieved
10 by applying the algorithm for finding the border outline in both the old and new skin images based on the same color range.

In Figs. 11-12, there are illustrated typical display screens of a skin image which has been sampled to reduce its size. In Figs. 11-12, respectively, there are shown former and more recent versions of the skin
15 image and the area under study. This is an important aspect of the diagnostic technique since it enables early detection of new lesions or changes in existing ones. The dermatologist or health professional can adjust the threshold value of color which determines which colors will comprise the lesions. The comparison between the bitmaps is based on this
20 threshold value, to reveal changes in existing lesions, and detecting new ones. The value selected for the color parameter is shown on the scale 120 under the display, and mouse 16 can be used to vary the value. As shown in Figs. 11-12, changes in the existing lesions (1-8) can be seen and compared, and new lesion (9) can be detected.

25 After the threshold value is adjusted, the dermal diagnostic analysis system 10 executes an algorithm (see flowchart in Figs. 13a-b) to find all the existing lesions, and display them in list 122 along with the related parameter values.

The dermatologist or health professional then supplies three image
30 points for alignment of the old and new skin images. The dermal

diagnostic analysis system 10 can then find all the new lesions appearing in the new image, by comparing the lists of lesions generated with respect to the old and new images.

In Fig. 13a, there is shown a flowchart representing the computer processor 14 operation in finding the number of lesions on a particular region of the skin. The algorithm detects and counts all the lesions in the area of interest. The method of finding all of the points comprising a single lesion is explained in detail by the flowchart of Fig. 13b, where each lesion point is marked as occupied.

10 In Fig. 13a, the operation begins in block 130, where each point in the image bit map is sequentially read. In block 132, a non-occupied point "a" is identified which is contained in a lesion, and in block 134, each point connected with "a" is read and marked occupied. In block 136, the lesion is added to the list of existing lesions and its characteristic
15 parameters are read and stored.

In Fig. 13b, there is shown a flowchart representing the computer processor 14 operation in scanning the connectivity component of point "a". In block 138, a list L is defined as a search list of points, where each point includes, in addition to its coordinates x,y in the bitmap, the
20 direction of toward the next point in the list. In block 140, the initial point "a" is inputted from the algorithm of Fig. 13a (block 134). In block 142, it is determined if there are neighboring points to "a" which are unoccupied and contained in a lesion. If there are, in block 144 the first neighbor point in the clockwise direction is stored in "b". Point "a" is
25 stored in list L in block 146, and marked as occupied. In block 148, point "b" is stored in "a", and the search is continued from there. If block 142 determines that there are no unoccupied neighboring points to "a" contained in the lesion, block 150 checks whether the list L is empty, and if it is, in block 152 point "a" is marked occupied, and the routine ends
30 in block 153. If L is not empty, in block 154, using point "a" the lesion

parameters are updated. Finally, in block 156, the last point in list L is found and stored in "a", and operation returns to block 142.

In Fig. 14, there is shown a flowchart representing the computer processor 14 operation as part of the calibration subsystem, to identify and
5 locate label 30. As stated previously, the calibration system utilizes a label 30 having reference colors which s photographed and processed with the skin image, to enable two-dimensional scaling of the skin image, independent of the camera photo angle or patient pose and distance from the camera. The calibration subsystem also provides color correction of the
10 skin image.

Preferably, label 30 is designed with a single black rectangle, and several gray rectangles. Based on this fact, the calibration subsystem is able to identify and detect the location of the label and perform the scaling and color correction functions. In block 160, $K \times K$ is defined as a
15 constant representing the size of the pixel search box. In block 162, a search is conducted to find the ten darkest boxes in the image, and in block 164, the darkest unchecked box coordinates are placed in storage at "R". In block 166, the color range of pixels in R is used to find the border outline of the image area containing R. In block 168, a local search
20 routine is performed to identify the remaining gray rectangles of the label adjacent to the border outline found in the previous step.

Assuming all the gray rectangles of the label were found, in block 170, then in block 172, the label is identified, and the procedure ends in block 174. If not, this indicates that the label was not found, and the
25 procedure returns to block 164, to continue examining the existing group of ten darkest boxes.

After the automatic identification of the label, the system calculates the size of the rectangles in it, and in accordance with the results of this calculation, the system establishes the pixel/mm ratio for scaling the

vertical and horizontal directions separately. This ratio also allows appropriate correction of the image dimensions.

The color calibration of the stored image is performed by the calibration subsystem in relation to the known colors of the label 30, so that appropriate compensation is provided for lighting conditions, etc. which may tend to affect the picture.

In Fig. 15, there is shown a flowchart representing the computer processor 14 operation in providing color correction as part of the calibration subsystem. In block 180, all the colors of the rectangles in the label are read sequentially, and in block 182, the gray level of the current and next rectangles are defined as G1 and G2, where $G2 > G1$ and there are no other gray levels of rectangles in between. In block 184, the actual gray levels of the current and next rectangles are defined as T(G1) and T(G2), and in block 186, a new color value is defined as the variable NEWCOL (r), and its value is set in block 188 for each r value, where $G1 \leq r \leq G2$, by the equation:

$$\frac{1}{r} \times [T(G1) + \frac{r-L1}{L2-L1} \times (T(G2) - T(G1))]$$

In block 190, each point in the image bitmap is read, and in block 192, the gray level of each point is defined as "G". Finally, in block 194, the color correction of each image bitmap point is made by multiplying the color correction factor NEWCOL(G) by the color value of each image bitmap point.

According to further features of the preferred embodiments, label 30 may feature any shape and size and may include any combination of reference colors.

Preferably, when using the present invention for monitoring melanoma, a set of labels 30 is provided, each label featuring a specific shape and reference colors so as to enable to detect changes over time in the shape and color of an existing mole or lesion.

5 Further, each label may feature a specific size so as to enable to accurately analyze skin regions of various sizes. For example, a label 30 of large dimensions allows to focus lens 13 of camera 12 on a larger skin region and to accurately monitor changes over time within such region, such as appearance of new moles and lesions.

10 According to the present invention, label 30 preferably features a specific size for calibrating the size of spots within a skin region, thereby enabling to determine size changes of existing spots and appearance of new spots within the skin region.

Further according to the present invention, the specific shapes, sizes
15 and reference colors of labels 30 are adapted so as to enable monitoring of different forms of skin disorders as well as burns, injuries and the like.

Further according to the present invention there is provided a data base including information such as reference bitmaps and parameters
20 relating to known pathological cases, for enabling the dermatologist to accurately diagnose the stage of the disease.

According to another embodiment (FIG. 16), a diagnostic analysis system according to the present invention includes a lens 13 remotely connected to a digital camera 12 by means of a wire 15 so as to allow a
25 patient to independently monitor the progress of the disease without the need to frequently visit a dermatologist. The results of such self-monitoring may be sent to the dermatologist for diagnosis.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

WHAT IS CLAIMED IS:

1. A dermal diagnostic analysis system comprising:
 - (a) an imaging element for capturing an image of a skin region;
 - (b) a processing element for converting said captured image to digital image information for analysis, display and storage; and
 - (c) a display element for displaying said digital image information,

wherein said digital image information is provided on said display element as a border outline of a dark area within said skin region in accordance with a pre-defined set of parameters, said digital image information including aspects of said displayed border outline such as its contour, and skin color variations of said area along a preselected section line segment, wherein said skin color variations are normalized with respect to a reference portion of said captured skin region image.

2. A dermal diagnostic analysis system comprising:
 - (a) an imaging element for capturing an image of a skin region;
 - (b) a processing element for converting said captured image to digital image information; and
 - (c) a display element for displaying said digital image information,

said digital image information including skin color variations within said skin region, wherein said skin color variations are normalized with respect to a reference portion of said captured skin region.

3. The dermal diagnostic analysis system of claim 2, wherein said reference portion is a detachable label having reference colors.

4. The dermal diagnostic analysis system of claim 2, wherein said reference portion is a detachable label having a specific shape.

5. The dermal diagnostic analysis system of claim 2, wherein said reference portion is a detachable label having a specific size.

6. The dermal diagnostic analysis system of claim 2, wherein said imaging element includes a camera having a lens remotely connected thereto.

7. The dermal diagnostic analysis system of claim 2, wherein said processing element includes a storage element for storing said digital image information.

8. The dermal diagnostic analysis system of claim 7, wherein said reference portion is a detachable label having reference colors for enabling monitoring of color changes of a spot within said skin region.

9. The dermal diagnostic analysis system of claim 7, wherein said reference portion is a detachable label having a specific shape for enabling monitoring of shape changes of a spot within said skin region.

10. The dermal diagnostic analysis system of claim 7, wherein said reference portion is a detachable label having a specific size for calibrating the size of spots within said skin region, thereby enabling to determine size changes of existing spots and appearance of new spots within said skin region.

11. A method for dermal diagnostic analysis, comprising:

- (a) capturing an image of a skin region by means of an imaging element;
- (b) converting said captured image to digital image information by means of a processing element; and
- (c) normalizing said digital information with respect to a reference portion of said captured skin region.

12. The method of claim 11, further comprising: displaying said digital image information on a display element.

13. The method of claim 11, further comprising: storing said digital image information.

14. The method of claim 13, further comprising: comparing a first digital image information with a second digital image information.

15. The method of claim 14, wherein said first and second digital image information relate to a former and more recent captured images of a skin region, thereby enabling to detect changes over time within said skin region.

16. The method of claim 15, wherein said reference portion is a detachable label having reference colors for enabling monitoring of color changes of a spot within said skin region.

17. The method of claim 15, wherein said reference portion is a detachable label having a specific shape for enabling monitoring of shape changes of a spot within said skin region.

18. The method of claim 15, wherein said reference portion is a detachable label having a specific size for calibrating the size of spots within said skin region, thereby enabling to determine size changes of existing spots and appearance of new spots within said skin region.

1/13

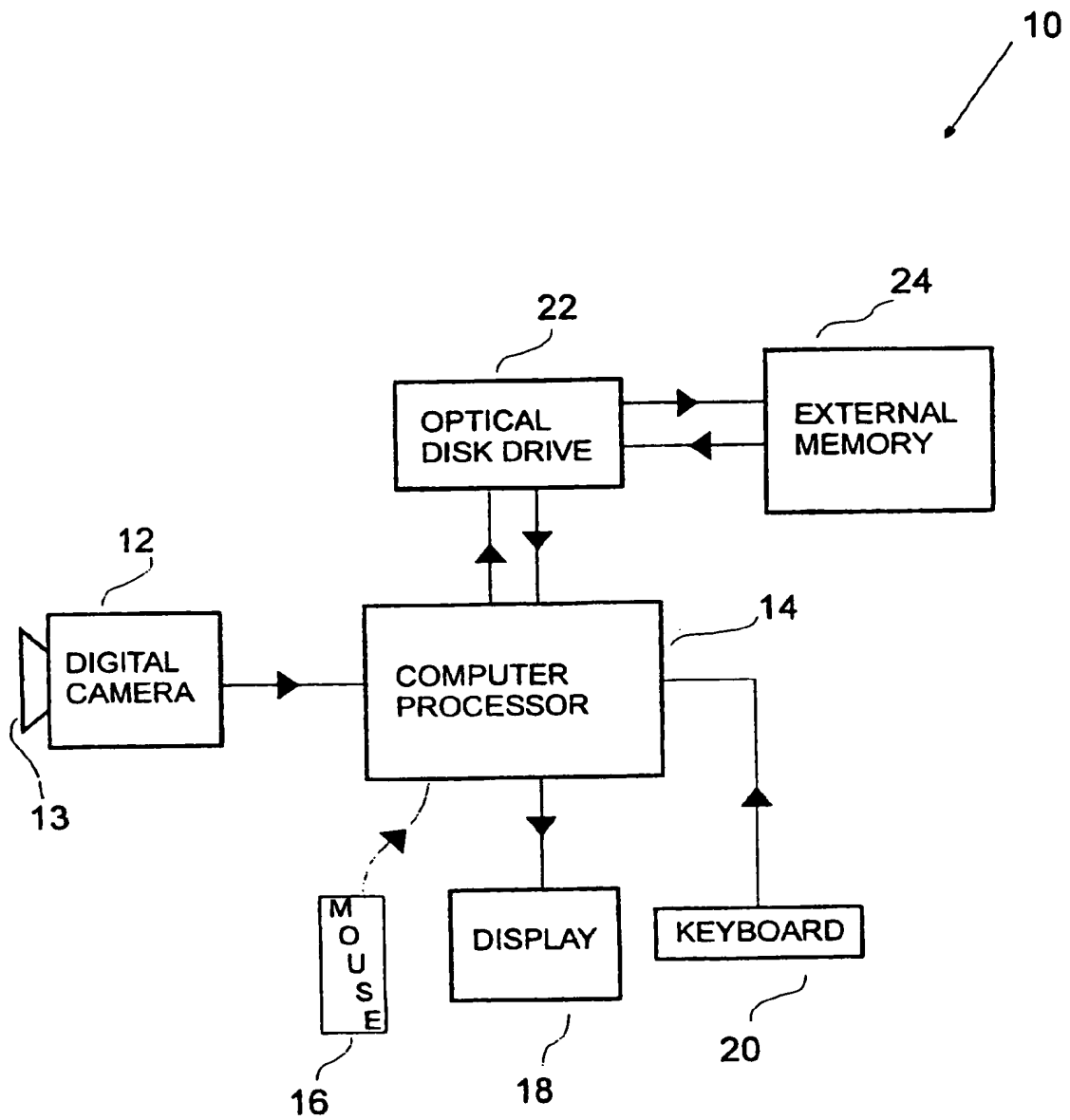


Fig. 1

2/13

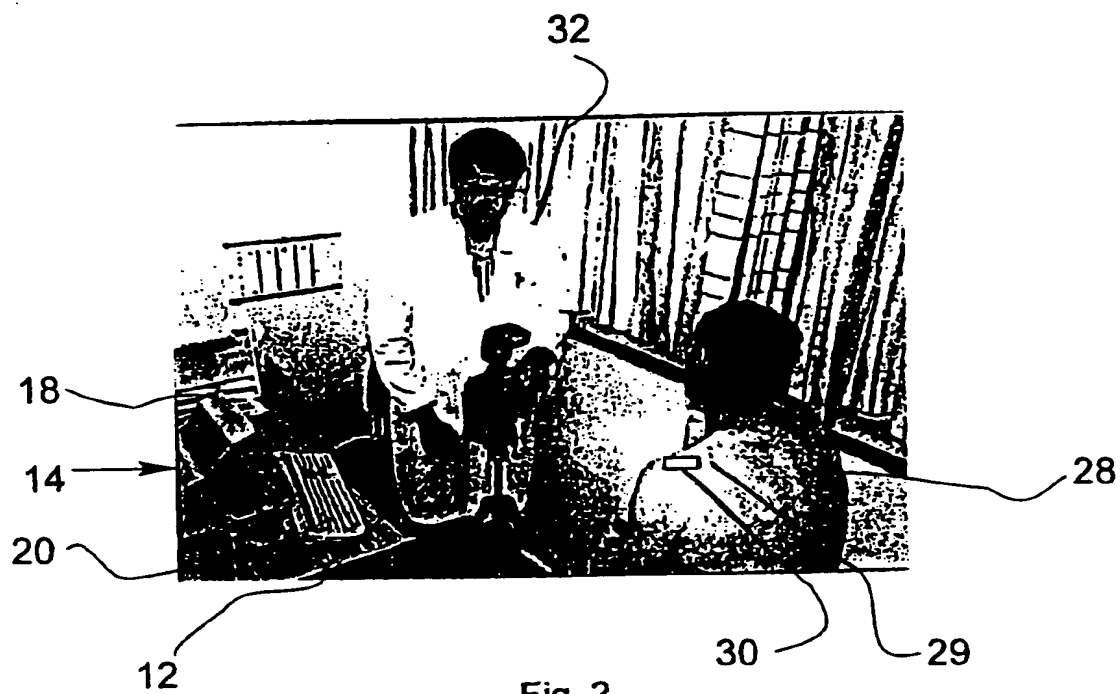


Fig. 2

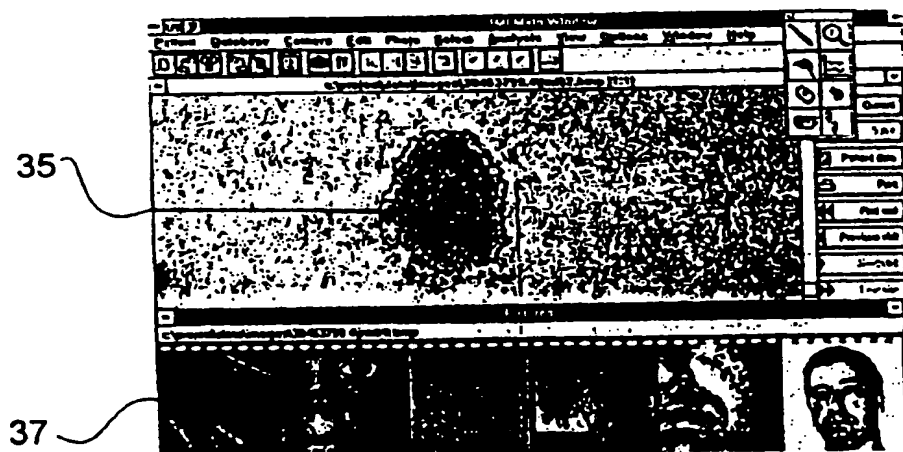


Fig. 3

3/13

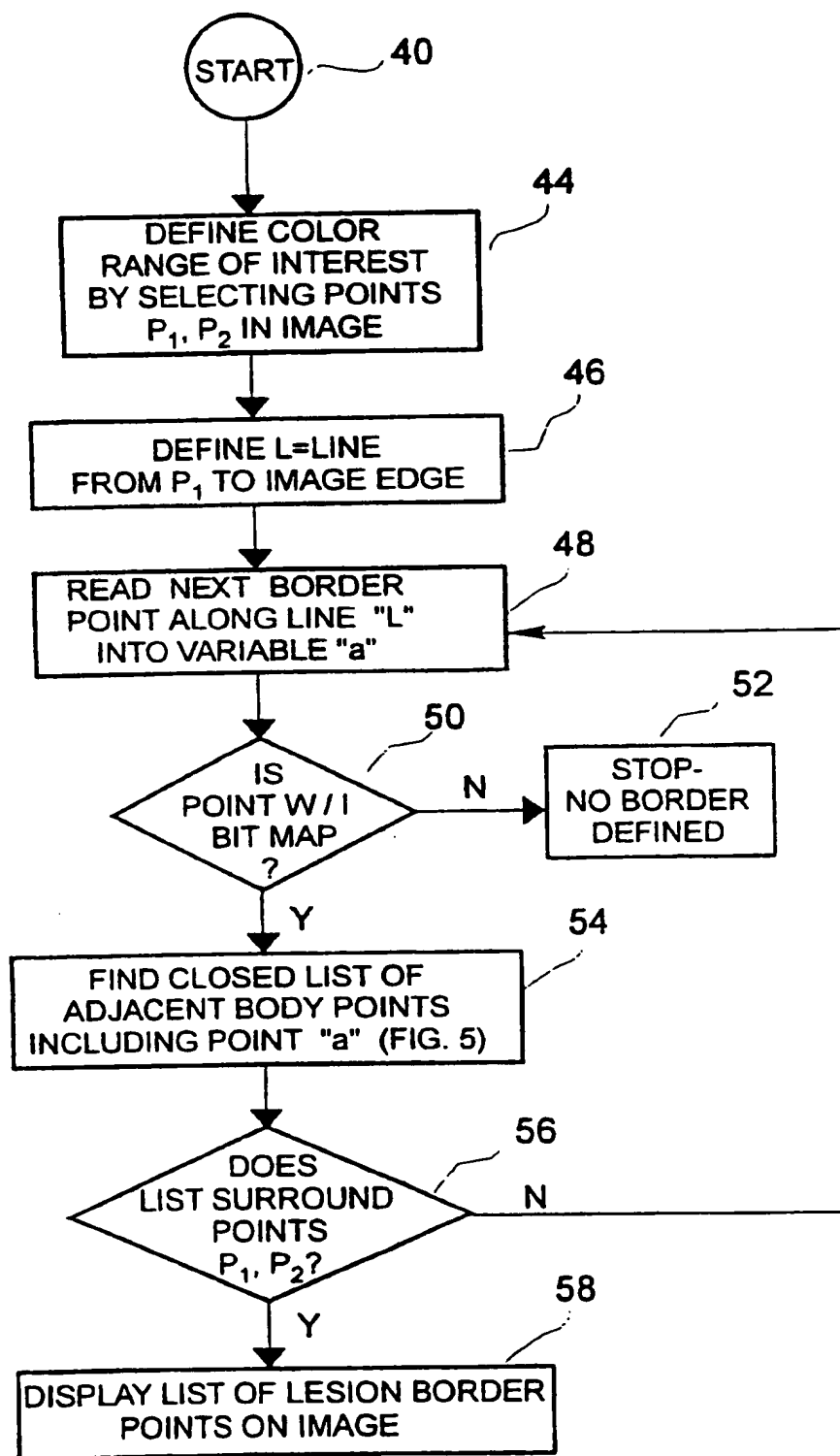
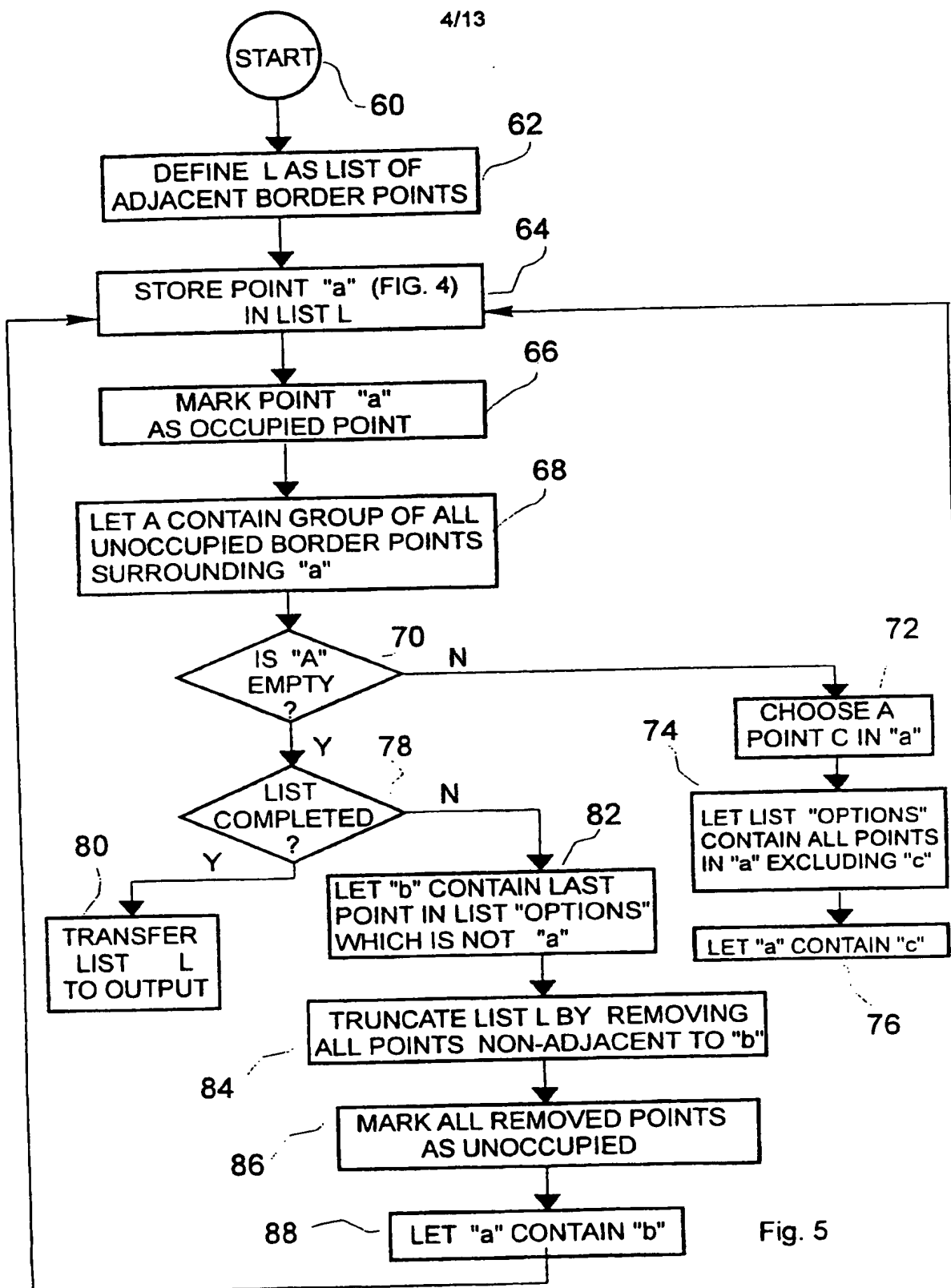


Fig. 4



5/13

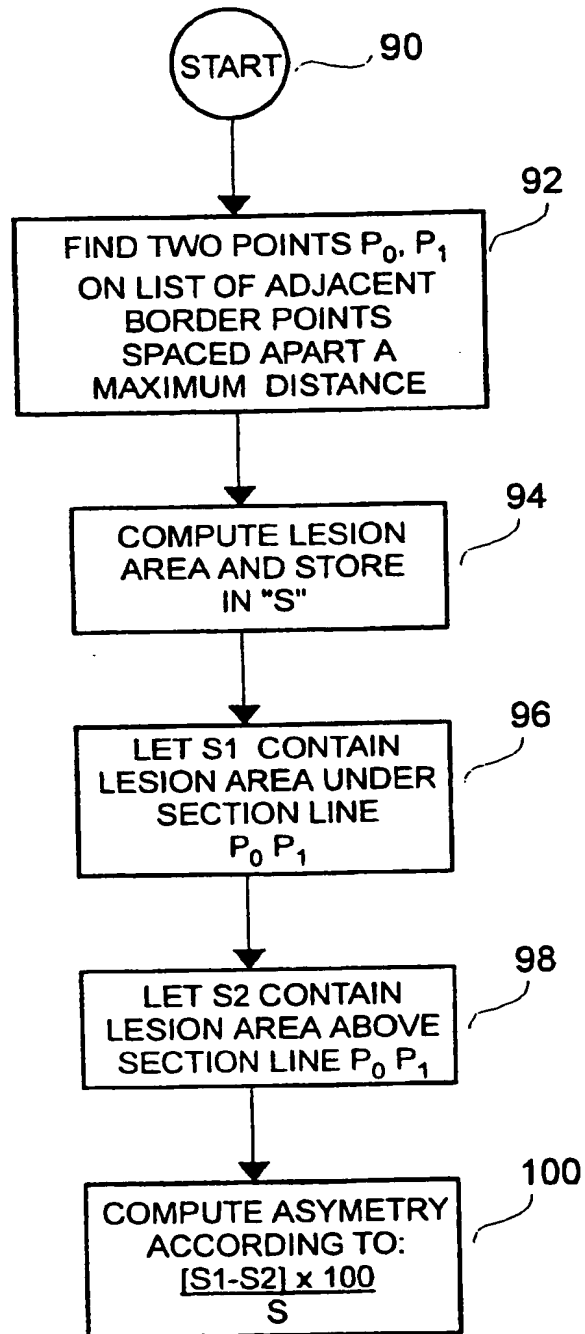


Fig. 6

6/13

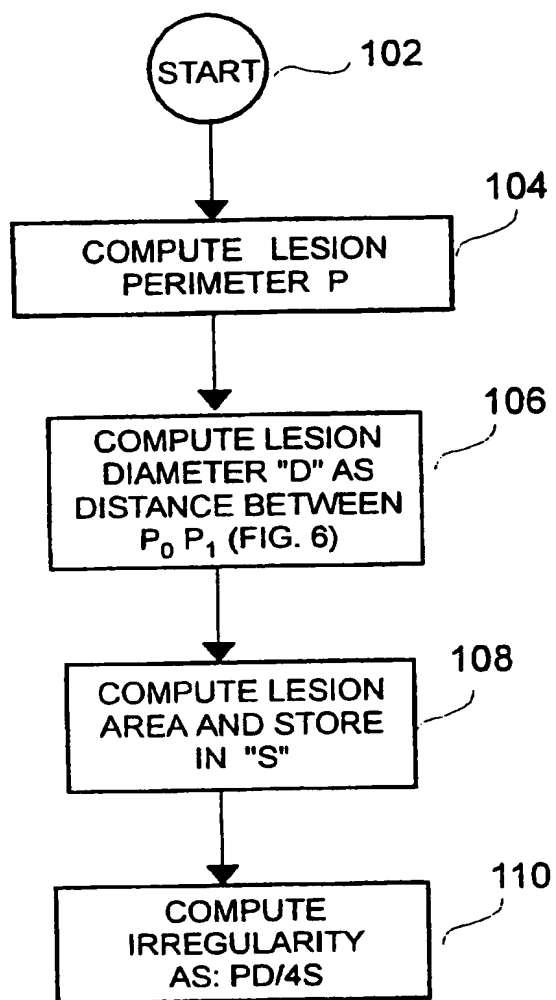


Fig. 7

7/13

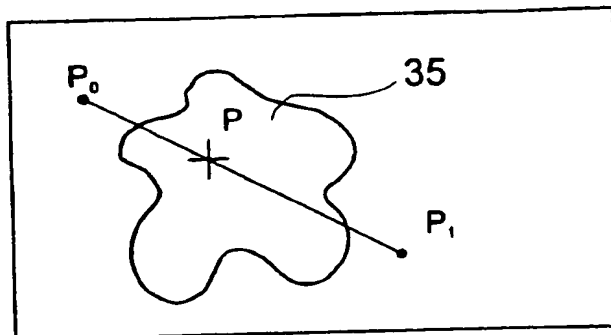


Fig. 8

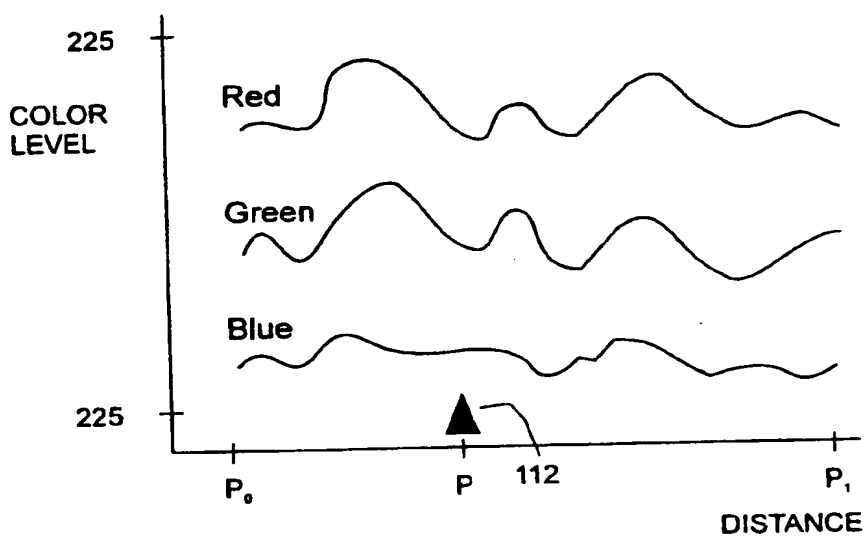


Fig. 9

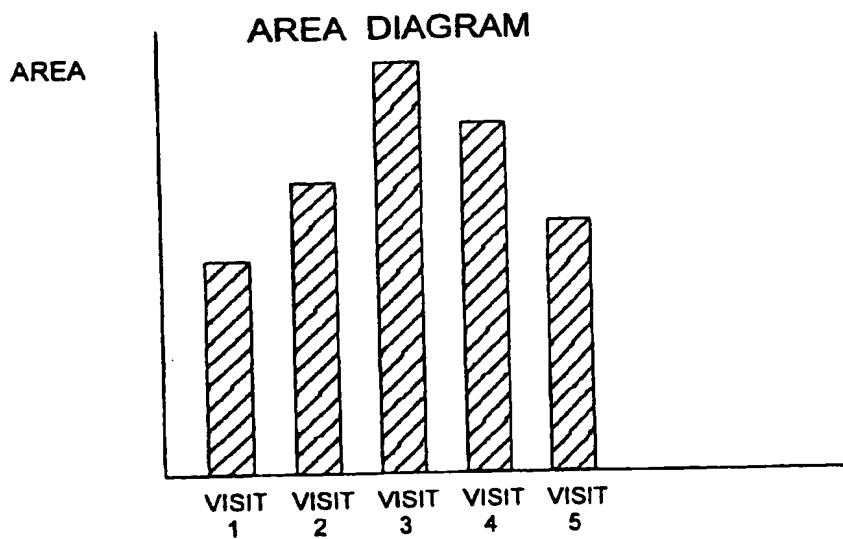


Fig. 10

8/13

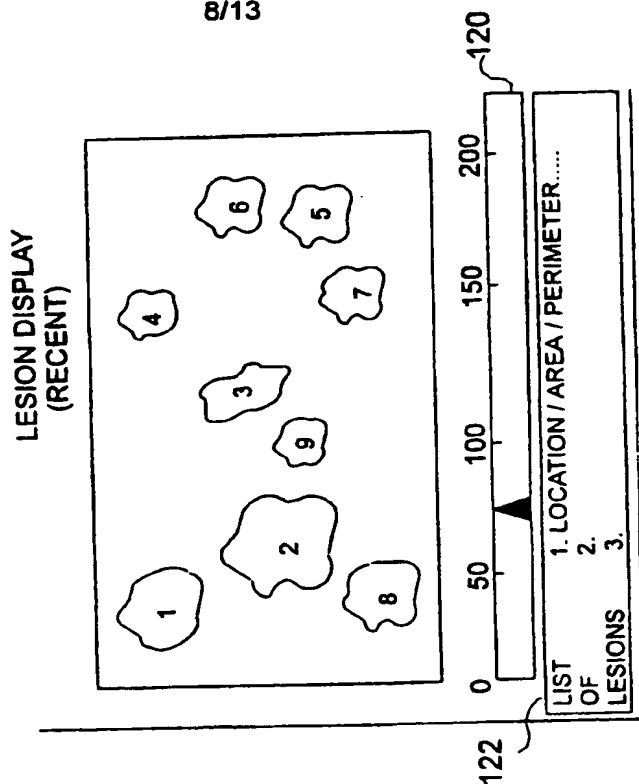


Fig. 12

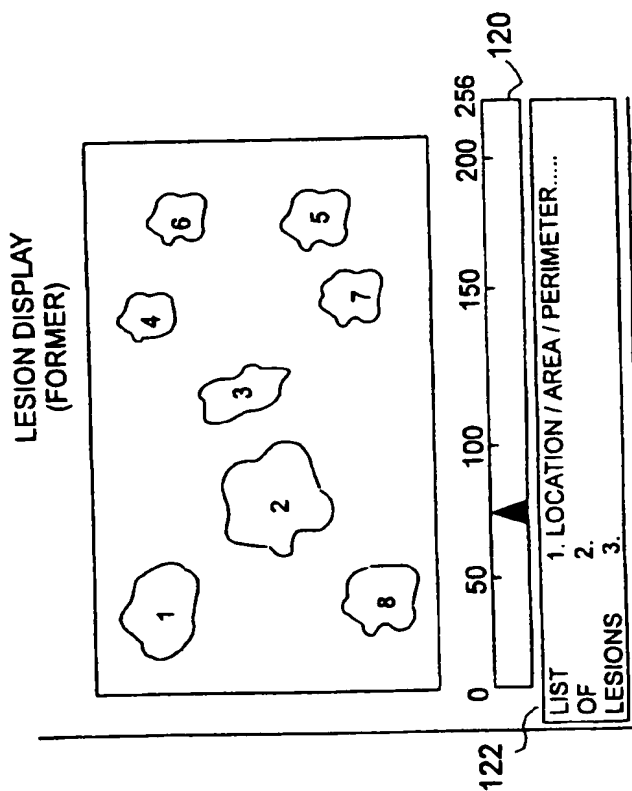


Fig. 11

9/13

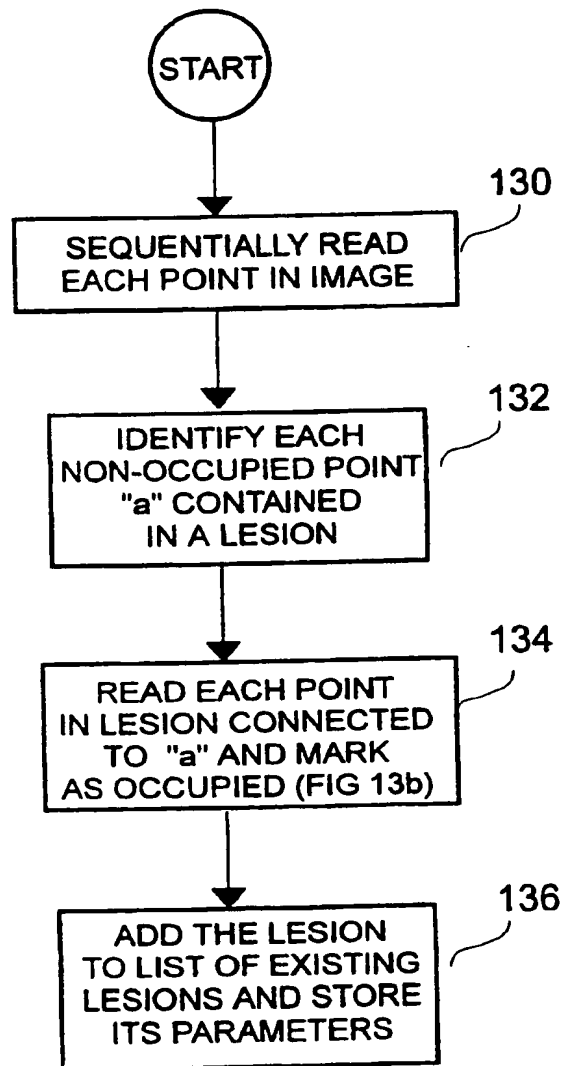


Fig. 13a

10/13

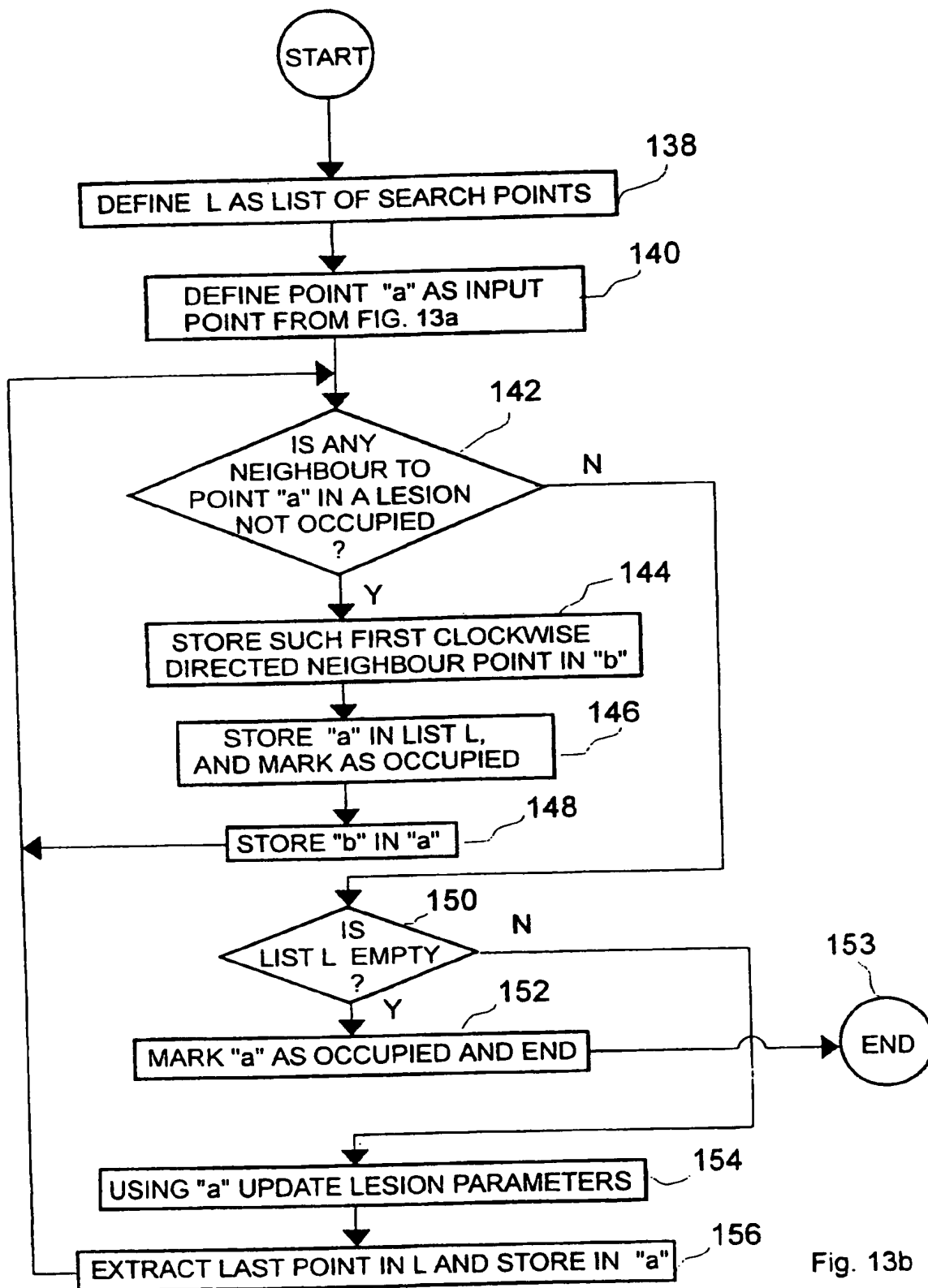


Fig. 13b

11/13

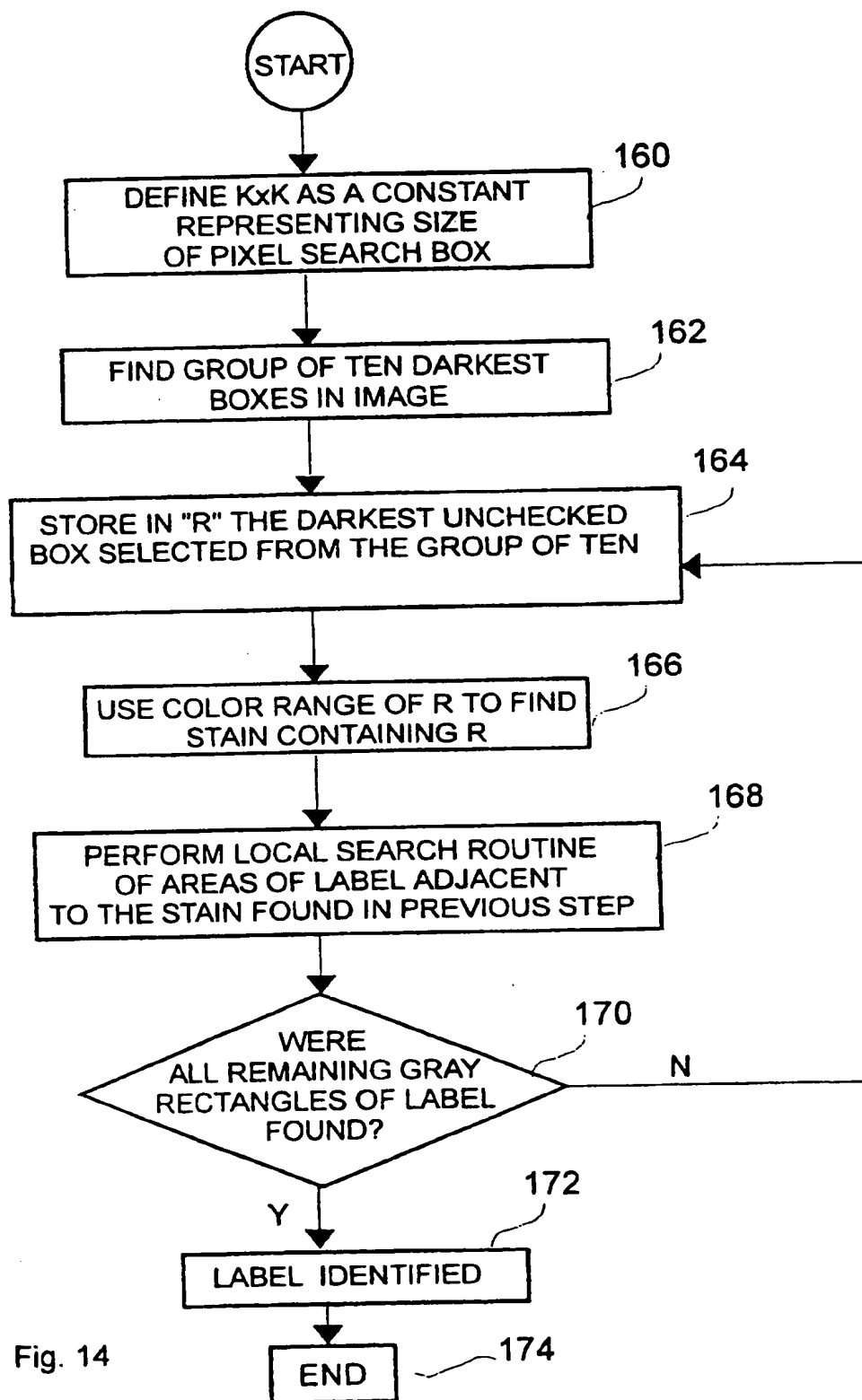
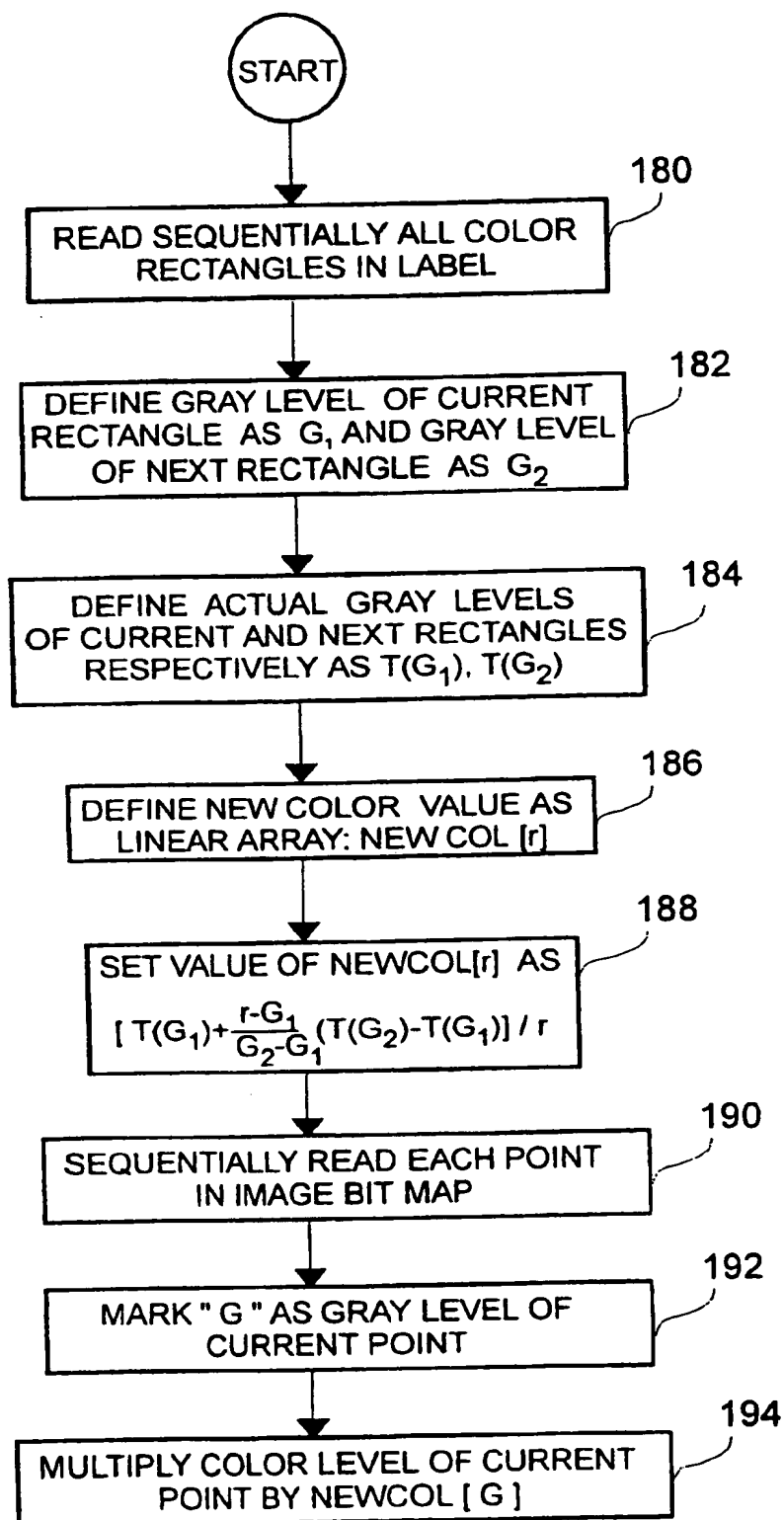


Fig. 14

12/13



13/13

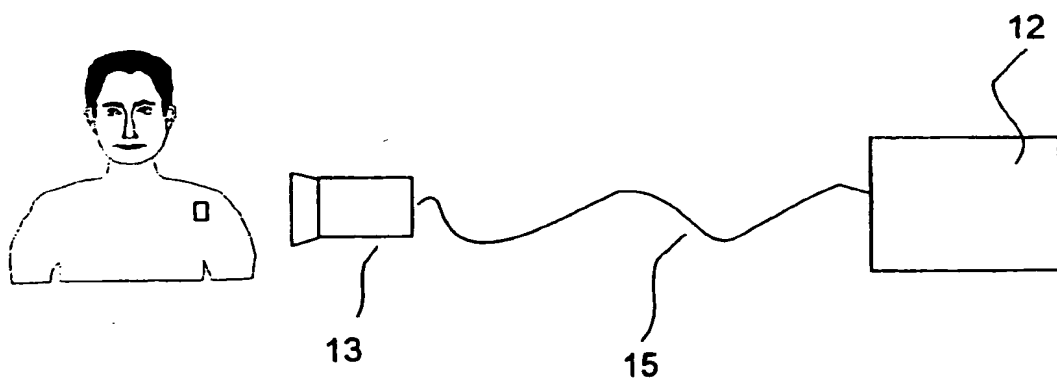


Fig. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL97/00187**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A61B 05/00

US CL : 128/653.1, 665, 922; 382/128

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/653.1, 664, 665, 920, 922; 382/128, 165, 199, 203, 266; 606/009

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

Search Terms: dermal, skin, camera, melanoma, cancer, outline, contour, color, shape

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,146,923 A (DHAWAN) 15 September 1992, Abstract; Fig. 5; col. 2, lines 45-58; and claims 21, 28 and 29.	1-18
X	US 5,241,468 A (KENET) 31 August 1993, Abstract, and claims 1 and 10.	1-18
X	US 5,016,173 A (KENET et al) 14 May 1991, Abstract; Figs. 2 and 3; col. 1, lines 32-52; col. 2, lines 52-64; col. 4, lines 8-25; col. 5, lines 52-58; col. 6, lines 64-68; and col. 10 line 40 to col. 11 line 20.	1-18
A	US 5,438,989 A (HOCHMAN et al) 08 August 1995, Abstract, and claim 1.	1-18
A	US 5,420,628 A (POULSEN et al.) 30 May 1995, Abstract; Fig. 1; and claim 1.	1-18

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

28 AUGUST 1997

Date of mailing of the international search report

12 SEP 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SHAWNA J. SHAW

Telephone No. (703) 308-2985

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL97/00187

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,133,020 A (GIGER et al) 21 July 1992, Abstract; Figs. 2 and 19; and claim 1.	1-18
A	US 5,420,628 (POULSEN et al) 30 May 1995, abstract, figure 1 and claim 1.	1-18
A	US 5,133,020 A (GIGER et al) 21 Jul 1992, abstract, figure 2 and 19 and claim 1.	1-18